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(71) Applicant *(for all designated States except US)*: ARCTURUS ENGINEERING, INC. [US/US]; 1220 Terra Bella Avenue, Mountain View, CA 94043 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: BAER, Thomas, M. [US/US]; 537 Drucilla Drive, Mountain View, CA 94040 (US).

(74) Agent: BRUCKNER, John, J.; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (US).

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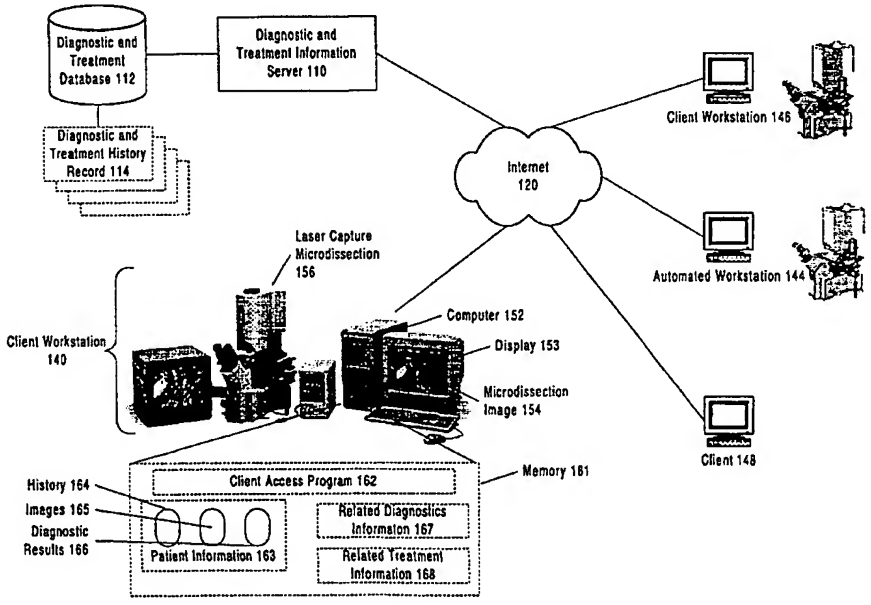
(54) Title: MEDICAL DIAGNOSTIC AND TREATMENT INFORMATION SYSTEM AND METHOD

(57) Abstract

An example of a method of accessing and presenting diagnostic and treatment information using a computer system is described. The system includes a client and a server. The client includes a program for accessing the server. In one example, the client sends patient background and initial diagnosis information to the server. The patient background information describes characteristics of a specific patient. The initial diagnosis describes the type and stage of the disease as determined by a person (in this example, a doctor). The server then searches its database of previous patient records to determine a set of records that correlate with the information from the client. The records represent patient histories describing patient backgrounds, diagnostic test results, treatments and success of treatments. From these records, the client displays the relationship between various diagnostic tests and the patient specific information. The doctor can then determine which diagnostic tests would be most appropriate for the patient. These tests can then be performed. The test results are then sent to the server where a new set of records is identified. The new set of records represents the records that correlate with the test results. The client then displays the relationship between the test results and various treatments. The doctor can then select the most appropriate treatment. Importantly, the doctor has been able to determine the appropriate diagnostics and treatments for a specific patient.



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# MEDICAL DIAGNOSTIC AND TREATMENT INFORMATION SYSTEM AND METHOD

## BACKGROUND OF THE INVENTION

### Field of the Invention

This invention relates to the field of medical database systems. In particular, the invention relates to systems for accessing medical diagnostic and treatment information.

### Description of the Related Art

Doctors diagnose and treat cancer by performing a number of tests on a patient and prescribing a treatment procedure. This process however is becoming increasingly complicated. The number of new techniques for diagnosing the different types and stages of cancer and the number of new types of treatments continue to increase. Additionally, research on the effectiveness of known treatments is being continuously updated. In addition, patient information that may be critical to determining effective treatments may not be readily apparent in a given case. All of these factors are contributing to an information overload for doctors.

Typically, a doctor first performs an initial diagnosis of the type of cancer and its stage of progression. To make this diagnosis, pathologists, for example, examine a sample of the cancerous tissue. The pathologist examines the pattern of the structure of the cell membranes and tissue (called the morphology of the tissue) to make an initial diagnosis of the type of cancer and its stage. From this initial diagnosis, the doctor may or may not prescribe any number of diagnostic tests.

One of the more interesting areas of diagnosis is in molecular diagnostics. These types of tests provide a roadmap of the genetic anomalies in the cancer cells. Given a specific type of anomaly, some chemotherapy treatments will be more effective than others. Importantly, the number of molecular tests that are available is expanding rapidly. Presently researchers are identifying the genetic anomalies that cause different types of cancers or tumors to grow. This provides doctors with a greater degree of

precision in determining the type and stage of a cancer. Each anomaly can be identified using a specific molecular test. However, this also makes the process of determining which type of diagnostics to apply to a given situation more difficult.

From the results of the tests, the doctor will then need to determine an appropriate treatment. In making this decision, the doctor needs to consider not only the many test results and the initial diagnosis, but patient specific factors such as age, weight, smoking status, etc. This is because some treatments may be ineffective or of marginal value to specific patients. For example, removal of a cancerous prostate may be an acceptable treatment for a 46 year old man, but not a 95 year old man. Thus, the determination of which treatment is most appropriate for a specific patient requires a complicated multi-parameter analysis where potentially hundreds of factors need be analyzed.

Therefore it would be desirable to have a system where the doctor could search for the latest and most effective diagnostics tests that could be performed for a given patient and then given the results of those tests, determine which treatment would be most appropriate.

To help with some of these problems, the National Institute of Health (NIH) has proposed a database system, accessible from the worldwide web, to access the latest published research data. The system provides a worldwide web interface so researchers can access information directly from the database. The database would include laser capture microdissection (LCM) information. (LCM is a technique used by researchers for performing molecular diagnostic tests. LCM allows doctors to capture individual cells, or groups of cells, of cancerous tissue. These cells can then be used in molecular diagnostic tests.) The database would include images of tissue biopsies with explanations of how the LCM should be performed on specific tissues. A number of LCM systems having automated processing are connected to the system. It is further stated that the database would link specimen archives with data and images of LCM procedures and molecular analysis already performed on those samples. The results, and link to the publications, would then be accessible following publication of the results. Importantly the NIH system provides researchers with a large source of information. As noted before, having the information available is but a small part of the problem. What

is needed is a system that allows the doctors to determine what diagnostics would be most appropriate for a given patient, and which types of treatments, given the results of the diagnostics, would be most appropriate. The NIH system may provide too much information and requires the doctor to determine the relationships between all that information himself or herself.

Therefore, what is needed is a system that helps doctors sort through the growing amounts of diagnostics and treatment information so that patient specific diagnostics and treatments can be determined. It is desirable that the system allows the doctor to determine which diagnostic tests will provide the most relevant results for a given patient. It is also desirable that the system provides information about the types of treatments available that are most relevant to a specific patient. It is also desirable that the system be capable of being dynamically updated to incorporate new diagnostics and treatment information.

## SUMMARY OF THE INVENTION

One embodiment of the invention includes a method of accessing and presenting diagnostic and treatment information using a computer system. The system includes a client and a server. The client includes a program for accessing the server. In this embodiment, the client sends patient background and initial diagnosis information to the server. The patient background information describes characteristics of a specific patient. The initial diagnosis describes the type and stage of the disease as determined by a person (in this example, a doctor). The server then searches its database of previous patient records to determine a set of records that correlate with the information from the client. The records represent patient histories describing patient backgrounds, diagnostic test results, treatments and success of treatments. From these records, the client displays the relationship between various diagnostic tests and the patient specific information. The doctor can then determine which diagnostic tests would be most appropriate for the patient and would provide the maximum amount of information by comparing the individual patient's test results with other patients in the data base that have similar initial diagnoses. These tests can then be performed. The test results are then sent to the server where a new set of records is identified. The new set of records represents the

records that have specific diagnostic test results (e.g., molecular diagnostic data) that correlate with the test results of the patient. The client then displays the relationship between the test results and various treatments. The doctor can then select the most appropriate treatment. Importantly, the doctor has been able to determine the appropriate diagnostics (e.g., those tests that yield the most information about the state of the disease) and treatments for a specific patient (e.g., those therapies/treatments that have the most benefit for the patient).

In some embodiments of the invention, the client displays the relationship between various diagnostic tests and the patient specific information so that the doctor can determine the correlation between a specific indicator and the life expectancy of a patient. In this way, the doctor can easily determine the relationship between an indicator, determined by a test and its relationship to a particular disease. The doctor can prescribe diagnostic tests for indicators that relate to a particular disease. In some embodiments, the client displays the treatment information as a graph of life expectancies for numerous treatment types. From the display, the doctor and patient can select the treatment type most suited for that patient.

In some embodiments of the invention, only the diagnostics information is accessible from the server. Such embodiments allow doctors to determine which tests should be applied for a specific patient. In other embodiments of the invention, only the treatment information is accessible from the server. Such embodiments allow doctors to analyze multi-parameter test results to determine the most appropriate treatments for a patient.

In some embodiments of the invention, information supplied by doctors is reviewed and stored in the server database for use in subsequent searches. In this way, the information available to the server grows. Additionally, research information can be included in the server database.

In some embodiments of the invention, the server can save information about the steps performed at the client. This allows the doctors to review their past procedures and assessments. In some embodiments, insurance companies and health maintenance organizations can access the information in the server to help speed the approval of diagnostic tests and/or treatments.

In some embodiments of the invention, the diagnostic tests described in the system include Laser Capture Microdissection (LCM) protocols.

In some embodiments, the server can provide the client with links to information about new diagnostics and treatments.

## BRIEF DESCRIPTION OF THE FIGURES

Figure 1 illustrates a system for accessing diagnostic and treatment information.

Figure 2 illustrates an example method of using the system of Figure 1.

Figure 3 illustrates an example of diagnostic information retrieved from the system of Figure 1.

Figure 4 illustrates an example of treatment information retrieved from the system of Figure 1.

Figure 5 illustrates a system for validating diagnoses and treatments information.

## DETAILED DESCRIPTION

### A. Definitions

The following provides some definitions of terms used herein.

Computer – anything that can execute a program. A computer can include other computers. Computers have at least one processor and access to some storage.

Program – one or more instructions for execution by a computer.

Doctor – means any health care professional. Doctor is referred to throughout the description but any user could substitute.

Cancer – a disease. Cancer is referred to throughout the description but any disease or medical condition could substitute.

### B. System Overview

The following sections describe various embodiments of the invention. The description is organized as follows. First, a general overview of the system is provided. Next, a detailed description of each of the elements of the system is given. Next, an

example method of using the elements of the system is given with a discussion of some example displays. Finally, alternative embodiments are discussed.

Figure 1 illustrates an embodiment of a system for accessing and displaying diagnostic and treatment information. The system includes a number of clients attached to at least one server. Doctors, or other medical practitioners, using the clients, can access information at the server to determine appropriate diagnostic tests and/or treatments for a specific patient. Importantly, Figure 1 illustrates an integrated system for accessing the diagnostics and treatment information and displaying that information in a way that is most useful for the doctor.

To use the system, doctors enter information about a specific patient and make initial diagnosis of a patient's disease. This can include determining the type and stage of a particular cancer that the patient may have. This information can be sent to the server. The server determines a set of records of previous patients that had similar backgrounds and diagnoses. The records are processed so that the client can display the relationship between various indicators and the specific patient information. The indicators correspond to particular anomalies in the genetic code of the cancer cells. In addition, the indicators correspond to diagnostic tests that reveal the presence of these genetic anomalies. Importantly, the doctor can determine which tests would yield the maximum amount of information by comparison with the data base and thus would be most appropriate for the patient given the initial diagnosis and background information.

The tests would then be performed and the results sent to the server. The server would then find a new set of records that have similar diagnostic results and background patient information. The records are processed to show the various treatment types with the corresponding life expectancy for a patient following the treatment. The doctor and patient can review these results and chose a course of treatment that best suits the patient.

The elements of Figure 1 are now listed and their configuration described. Figure 1 includes a diagnostic and treatment information server 110, a client workstation 140, a client 148, an automated workstation 144, and a client workstation 146. These elements are all coupled in communication via the Internet 120. The diagnostic and treatment information server 110 is coupled to a diagnostic and treatment database 112.

The diagnostic and treatment database 112 includes a number of records, for example the diagnostic and treatment history record 114. Turning to the workstations, the client workstation 140 includes a laser capture microdissection (LCM) station 156 and a computer 152. The computer 152 includes a display 153 showing a microdissection image 154. The computer 152 also includes a memory 161. The memory 161 includes, among many other things, a client access program 162, a patient information 163, a related diagnostics information 167, and a related treatment information 168.

The following paragraphs describe each of the elements of Figure 1 in detail.

The diagnostic and treatment information server 110 represents a web site server that can respond to requests from clients. The server 110 can include one or more programs running on one or more computers. These programs work together to respond to requests from clients. Examples of such servers are Apache web servers running on Sun workstations, Microsoft and/or Netscape servers running on personal computers, or any other type of program/computer combination that could serve client requests. What is important is that the server 110 can respond to requests from clients. The requests would include requests for information about sets of patient records that would relate to specific patient information. Thus, the server 110 includes a program for initiating requests and processing the results for use by the clients.

The diagnostics and treatment database 112 represents a database of diagnostics and treatment information that the server 110 can use to respond to the requests from clients. The diagnostics and treatment database 112 can include a relational database such as is available from Oracle, Informix, Microsoft, and/or IBM. Alternatively, the diagnostics and treatment database 112 can be an object database or a proprietary program. However, any program that can store the patient history information and supply that information upon request will substitute.

The diagnostics and treatment history record 114 is an example of the type of information that can be included in the diagnostic and treatment database 112. The diagnostic and treatment history record 114 can include information about a specific patient such as their background, their diagnosis, the results from various diagnostic tests, and/or their present health status. The diagnostic and treatment database 112 can also include other types of information corresponding to research results, new diagnostic

tests, different and new treatments, new indicators that can be found using new diagnostic tests, links to research sites, links to laboratories that can perform tests, etc.

Turning to the clients, various clients can be included in the system. The client 148 represents a basic client computer that can be coupled to the Internet 120 and used by a doctor. The important elements of the client 148 is that it has a processor and a memory that can execute programs and can communicate with the server 110 over a network. For example, the client 148 could be a personal computer running a browser. Alternatively, the client 148 could be a personal computer running a specialized application for accessing the information from the server 110. The client 148 typically will include a display for displaying information to the doctor. Note that the client 148 can be connected to the Internet 120 directly, or through a network of other computers, such as a proxy server, or some other communications network.

The client workstation 146 and the client workstation 140 are representative of workstations in which a doctor can perform initial diagnosis of a patient, can access the server 110, and begin diagnostics testing of tissue samples of a patient. This type of workstation is particularly useful to doctors because they can perform many of the steps in one sitting. The client workstation 140 can include a laser capture microdissection station 156, such as the ARC-200™ station available from Arcturus Engineering, Inc. of Mountain View, California. The laser capture microdissection (LCM) station 156 allows a doctor to capture individual, or groups, of cells from a sample tissue of a patient. The LCM station 156 also allows the doctor to visually inspect and archive the sample, providing a means for obtaining a preliminary diagnosis of the biopsy sample. The computer 152 corresponds to a computer that can be used to access, manipulate, and store information from the LCM station 156. In the example of Figure 1, the computer 152 uses the display 153 to display the microdissection image 154.

The memory 161 represents the type of storage areas available to the computer 152. The memory 161 can be local memory, or it can be memory on a server, or in a shared memory system. What is important is that the computer 152 has some area in which to store information.

The client access program 162 represents a program for accessing the server 110. The client access program 162 can also include functions such as accessing patient

information from patient information systems, accessing information from the LCM station 156, or for prompting a doctor for patient information. The client access program 162 can take the patient information 163 and provide it through the Internet 120 to the server 110. Examples of client access program 162 can be a proprietary program or simply a browser program.

The patient information 163 represents an example of information that may be obtained about a patient (the computer 152 may include patient information about multiple patients). The patient information 163 could represent a part of a record that will ultimately be stored in the database 112, or a number of text fields and/or other fields representing patient history and other related information. In this example, the patient information 163 includes a specific patient's history 164, any images 165 of tissue samples (e.g., the microdissection image 154), and any diagnostics results 166 from diagnostic tests performed on the patient. Note that not all of this information may be available for a particular patient at any given time. For example if the information is for a new patient, then the history 164 may be included, but no images 165 or diagnostic results 166 would be available.

The patient history 164 can include a patient's name and patient ID number, information such as age, sex, smoking status, weight, height, race and/or initial diagnosis.

The images 165 can include images of biopsies of tissue samples from the patient. These images can be jpegs, GIFs, or any other digital images of the patient's tissue. The images 165 represent images that a doctor will typically be able to use to determine the morphology of the cancer.

The related diagnostics information 167 represents information about diagnostic tests and indicators that relates directly to the patient information 163. Examples of diagnostics information can include indicator types, corresponding tests, protocols for performing the tests, background information about the tests, and/or side effects information. From the related diagnostics information 167, the doctor can determine which set of diagnostics test would be most valuable for a particular patient as described in the patient information 163.

The related treatment information 168 illustrates the type of treatments that may be most applicable to the patient information 163. The related treatment information 168 can include treatment types, life expectancies, treatment information, and related links. From the related treatment information 168, the doctor can determine which treatments may be most useful for a particular patient.

The Internet 120 represents a communications network by which the various elements of Figure 1 can communicate. Other types of networks can be used, such as local area networks or wide area networks using proprietary communications technology. In some embodiments of the invention, the clients can make requests of the server 110 using the Hypertext Transfer Protocol (HTTP). To the clients, the server 110 represents a web site from which information can be extracted. The server 110 can generate HTML formatted web pages in response to a request from the clients. However, other embodiments of the invention include other systems for communicating between the clients and the server 110. HTML based embodiments represent systems that transfer relatively simple information from the server 110 to the clients. Other embodiments of the invention allow the server 110 to serve information with semantic meaning, such as may be provided by an XML formatted data. This would allow a heterogeneous network of clients to access the server 110 and still be able to process the information received from that server. In some embodiments, the XML Metadata Interchange Format (XMI) is used to store and share object programming at the clients and server. Other embodiments of the invention can include other network communications and protocols to be used for transferring the information between the clients and servers. What is important is that there is someway in which information from the server can be requested and the results can be sent back to the clients.

C. Diagnostic and Treatment Information Accessing

The following describes an example method using the system of Figure 1 to access diagnostic and treatment information. By using this example method, a doctor can determine appropriate diagnostics for a specific patient and determine the type of treatments that would be most appropriate for the patient.

At block 210, the patient background information is obtained. This includes accessing the patient history 164. This can be done by accessing patient records, prompting the doctor for patient background, or some other technique whereby the background information for the patient is obtained. For example, the server 110 could provide an HTML formatted questionnaire at the client and the doctor could fill in the fields. Alternatively, the client or server 110 could query a patient record system for the background history.

Turning to a specific example, a doctor may enter the following information into a client about a patient.

Age: 46

Sex: Male

Residence: Mountain View, California

At block 220, the images of the patient's tumor tissue are captured. In one embodiment of the invention, the client workstation 140, using the LCM station 156, can capture images on the computer 152. Other embodiments of the invention allow images to be captured at other workstations or to be accessed from other locations or files. What is important is that some type of image of the sample tissue is captured so that the doctor can perform an initial diagnosis of the type and stage of the cancer. Alternatively, the images need not be captured, so long as an initial diagnosis can be made.

The doctor makes an initial diagnosis. For example, the doctor may make an initial diagnosis of a prostate cancer Gleason level 2 PIN lesion.

The system now provides the doctor with information so that he/she can determine what diagnostics to perform.

At block 240, the client sends the patient information 163, including the history 164 and any initial diagnosis, to the server 110. In some embodiments, the image information will not be sent to the server 110. In other embodiments, the image data will be sent up to the server 110 for further use in finding related records.

Next, at block 250, the server 110 generates a query from the information received from the client 140. This can be done in a number of ways, but importantly, the server 110 is attempting to identify records in the database 112 that are similar enough

to be relevant to the doctor. Relevant records would be those that match the general background of the patient and the initial diagnosis. The request from the client corresponds to a request for the records in the database that correspond to, or have a potential significance, for showing the pathogenesis of a disease for the particular patient.

Relevant records can be determined by ranges set around fields in the records. The ranges provide a soft cut off for relevant records in the database. The soft cut off is based upon a qualitative assessment of what information is relevant to the doctor. In some embodiments, the doctor can specify the ranges around the patient information. Default values may be used if no values are provided. The doctor can interactively change the ranges in some embodiments to determine how the changes will effect the number of records found. Similarly, indications of the number of found records can be provided as intermediary values to allow the doctor to understand how many records would be located by the server 110 for any given search.

In one embodiment of the invention, the server 110 issues one or more SQL queries to the database 112. The database 112 returns a number of records such as the diagnostic and treatment history record 114. The server 110 can then format these records into one or more HTML formatted pages. Figure 3 illustrates an example of such an HTML page (described below).

At block 260, the client receives the HTML page and displays it for the doctor.

Figure 3 shows such a page. The diagnostics HTML page 300 includes the patient information 310 that corresponds to the patient information 163. The page includes the initial diagnosis and the number of records found in the database 112 (shown as found records indicator 340). The diagnostics HTML page 300 also includes an indicators graph 320. The indicators graph 320 shows various indicators along the x-axis and their corresponding significance to the patient information 310 along the y-axis. An indicator with a high significance indicates that performing a test to determine whether such an indicator is present will be useful in determining the type or stage of the disease. In this example, the most significant indicators are shown on the left hand side of the graph and the least significant indicators are shown on the right hand side of the graph. However, in other embodiments of the invention, different types of displays are

used to help doctors identify important indicators. Note that the significance of various indicators can be determined by a weighting process. Note that the number of indicators has been reduced significantly in this example. Hundreds of potential indicators could be shown. Alternatively, instead of, or in addition to, the indicators, groupings of related tests could be shown.

Additionally, the diagnostics HTML page 300 includes links associated with each indicator, as shown by the indicator to protocol link 330. Each link can link to information about the indicator and the different tests or protocols that can be used to test for the existence of the indicator. In some embodiments, the links describe the protocol use for with LCM. For example, the server 110 can provide information about the type of microdissection to use given the morphology of the disease as diagnosed by the doctor. Depending on the type of cancer and its location in the body, different types of samples may be more appropriate. For example, if the cancer is more invasive, then samples from two different areas may be more valuable. The server 110 could indicate this type of suggested sampling at the workstation. This is optional.

Returning to the example above, the information that might be relevant to a doctor may be all male patients in the age range 40 to 55 having the same Gleason level. This information would be sent to the server 110. The server 110 would format one or more searches for the database 112. The database 112 would supply the results of the searches to the server 110. The server 110 would then format the results in HTML and send the results to the client.

At this point, the doctor can select the tests that are going to be most significant in determining the type and stage of cancer the patient has. Note that the selection process is important because it may not be practicable to perform a large number of tests. To perform many types of tests, the doctors will need to replicate large amounts of the genetic material. Given possibly hundreds of tests, it is desirable that the doctor be able to identify the few dozen tests that are most relevant to a patient.

The molecular tests can then be performed. In some embodiments of the invention, LCM is used to select individual cells from the tissue samples for use in the tests. Thus, the doctor can perform the initial diagnosis, determine the set of tests to perform, and extract the cells needed to perform the tests all at one location.

The test results represent multi-parameter information of the molecular make up of the tumor sample. Additional information from other kinds of tests can also be included such as cholesterol, etc.

Once the tests have been performed, the results can be used to determine which type of treatment would be most suitable for the patient. At block 270, the client can send the diagnostic results and patient background back to the server 110.

Returning to the example above, the tests provided results about the 46 year old male in Mountain View can be sent to the server 110. The information might include the molecular information about the DNA content of the tumor cell at important oncogenes such as MEM-2 and BCL-2, or the estrogen/progesterone receptor protein or gene expression levels, and a number of other factors. In the example above, the MEM-2 might be negative, the BCL-2 might be negative, and the ER/PR might be slightly positive, relative to a normal sample.

At block 280, the server now searches for records corresponding to the diagnostic results and patient background. This process is similar to block 250 except that now the diagnostic information can be used. The server 110 can format the results in a similar manner to that used at block 250. The found records illustrate the pathogenesis of the disease for the database sub-population that maps onto the patient's particular spectrum of diagnostics. The records can be sorted according to treatment type.

At block 290, the client displays the formatted HTML page corresponding to treatment possibilities and life expectancies for the patient. The doctor and patient can then select the most appropriate treatment for the patient.

Figure 4 illustrates an example of such a page. The treatment HTML page 400 includes the patient information 310, the number of found records indicator 440, a life expectancy graph 420, and some treatment links 430. The patient information 310 includes the history 164 and diagnostic results 166. The life expectancy graph 420 shows the life expectancy of a patient using various treatments. For example if no treatment is shown, one can see that the patient is expected to have a relatively short life. The treatment links 430 provide a legend for use by the doctor. Additionally, each treatment link 430 can be used to link the doctor to information about various

treatments. In this way, the doctor can become informed of new treatments that he or she may not have been aware of.

D. Diagnostic and Treatment Information Building

The system of Figure 1 allows for the addition of new patient history records and additional information to the database 112. In some embodiments, patient history records are reviewed for accuracy prior to inclusion in the database 112. Additionally, research information about new treatment can be included in the database 112. The new information can be included directly into the database 112 or can be accessed by the server 110 from other databases. This second approach may be more useful where research data from other databases is correlated with patient records from the database 112. In this case, the server 110 would only need to be changed to include new types of information instead of having to change the schema of the database 112.

By adding to verified information available to the server 110, the value of the information provided by the server 110 can increase.

E. Diagnostic and Treatment Validation

Figure 5 illustrates one embodiment of the system of Figure 1 where diagnosis and treatment information is accessible by an insurance company or health maintenance organization. The server 110 has been replaced by the server 510. The server 510 provides access to the patient records stored in the database 512. The patient records, such as the diagnostic and treatment history record 514, may include addition information that would be particularly interesting to an insurance company or a health maintenance organization. For example, tissue images, histories of procedures followed by doctors, information supplied by doctors, histories of searches performed by doctors, all for specific patients may be kept. In this way, the health maintenance organization or insurance company can access patient information and provide feedback about diagnostics and treatments. In particular, the health maintenance computer system 590, in conjunction with the diagnostic and treatment information server 510, could provide insurance companies with secure access to patient records and allow the health

maintenance computer system 590 to automatically approve specific types of diagnostic tests or treatments given information in the patient records database 512.

In some embodiments, the information sent to the server 510 is also sent to the health maintenance computer system 590. The results of the searches can then be provided to the system 590. The system can evaluate the information and automatically approve a particular test or treatment.

In addition, the database access process employed can be recorded and be kept as a part of the patient history to provide a historical record of the evaluation procedure performed by the physician. Also, an encrypted validation code could be sent to the HMO or insurance company and stored in the patient record providing validation that the physician used the database as a part of the diagnostic procedure. The history of the searches could also be reviewed.

F. Additional Embodiments

The following describes additional embodiments of the invention.

In some alternative embodiments, after block 250, the server 110 supplies images from some of the patient records for which a similar diagnosis has been found. This allows the doctor to compare his or her initial diagnosis with images from the patients having a similar diagnosis. The database server could then provide a number of pictures corresponding to the morphology of the subset of records found. These could be thumbnails provided to the doctor at the workstation to compare against the morphology of the sample which he or she is reviewing. This helps the doctor to classify or confirm the classification of the disease.

In some embodiments, prior to diagnostics information being sent to the client, the doctor could request that the server 110 provide information about patient outcomes. In these embodiments, the doctor can review the outcomes for himself or herself to determine the relevancy of particular diagnostics. The patient outcomes would indicate the survivability given the different types of genetic dislocations and corresponding treatments. This allows the doctor to understand whether a particular dislocation is more important than another. For example, if for a particular gene dislocation, all the outcomes fall on top of each other for any given treatment, then the doctor can

determine that the gene is not that important. Thus, the doctor does not need to have a molecular diagnosis done to determine whether there has been a dislocation of that gene. Thus, the database can help the doctor understand this information and determine which dislocations are the most important. The doctor then knows that the maximum amount of information from the database 112 will be obtained if he/she measures a given set of genes. Importantly, the information is being compared against the database records so it is actually a maximization of the information in the database that is being sought, not necessarily the right set of treatments or diagnosis.

In other embodiments of the invention, the server keeps a record of all of the interactions between a specific client and the server 110 (or all of the interactions regarding a specific patient by one or more doctors). The information can be used in liability checking to provide information about potential medical practice errors or omissions. Thus, the server 110 records the due diligence that the doctor performs in determining specific diagnosis. Alternatively, the client can record these interactions or some other database can record the interactions. Alternatively, only certain types of searches at the server 110 are noted.

The server 110 or the client can include an image signature for each of the tissue sample images captured. The signature could allow for identification of a image as being derived from a specific machine by a particular individual at a known time. Patient specific information can also be included with the image signature. Encryption techniques can be used to make it difficult to alter the signature without also corrupting the image. Such signatures can be helpful in identifying images. The signatures can be particularly useful where the images are not being transferred to the server 110 but may need to be accessed by a third party at a later date.

Other embodiments of the invention support other ways of presenting the diagnostics and treatment information in graphical form.

In some embodiments of the invention, the results of the searches are provided directly to the clients for manipulation. In some embodiments, the clients include programs for manipulating the results from the server so that doctors can view the results in different ways.

Some embodiments of the invention only include the diagnostics determination parts of the system while in other embodiments, only the treatment determination parts of the system are included.

Other embodiments of the invention include the activities at the client and/or the activities at the database and/or server. Some embodiments of the invention include computer readable media having one or more programs to implement the functions at the server. Alternatively, the programs could be included in an electromagnetic waveform.

Other embodiments of the invention include the process of reviewing diagnosis at the insurance company's computers. (In this description, insurance companies can be substituted for any insurer, or interested party, who would want to review the diagnosis information retrieved and/or treatment selection carried out using the system.)

Some embodiments of the invention can employ data mining techniques to identify affinities and relationships between data in the database. Visual, neural network, and other data mining techniques can be employed in various embodiments. For example, these techniques can help refine the similarity searching in finding similar patient histories. Additionally, these techniques can help weigh indicators or diagnostics tests to help doctors determine relevancy (e.g., cluster identification can be used to identify indicators with high relevance). Such techniques are described in Sholom M. Weiss, Nitin Indurklhya, "Predictive Data Mining: A Practical Guide," Academic Press/Morgan Kaufmann, 1997, Ruby L. Kennedy (Editor), "Solving Data Mining Problems Through Pattern Recognition," Prentice Hall, 1997, and "Data Mining Solutions: Methods and Tools for Solving Real-World Problems," John Wiley & Sons, 1998.

G. Conclusion

The foregoing description of various embodiments of the invention has been presented for purposes of illustration and description. It is not intended to limit the invention to the precise forms disclosed. Many modifications and equivalent arrangements are apparent.

## CLAIMS

What is claimed is:

1. A method of optimizing a portfolio of molecular diagnostic screening tests for a patient using a computer, the method comprising:

accessing patient specific information including initial diagnosis information and patient history information;

searching a database using the patient specific information to create a set of related case histories;

using the set of related case histories to determine a set of parameters, the set of parameters being used to determine a probable pathogenesis of a disease associated with the initial diagnosis; and

using the set of parameters to determine at least a first diagnostic test wherein the first diagnostic test corresponds to the probable pathogenesis of the disease.

2. The method of claim 1 wherein accessing the patient specific information includes accessing records in a database having the diagnosis information and the patient history information.

3. The method of claim 1 wherein the initial diagnosis information includes a definition of a type and a stage of a disease.

4. The method of claim 1 wherein the patient history information includes information about the age and sex of the patient.

5. The method of claim 1 further comprising capturing images of a biopsy of the patient and receiving the initial diagnosis at least partially from the captured images.

6. The method of claim 1 wherein searching the database includes searching the database for a set of records that have data similar to the initial diagnosis information and the patient history information.

7. The method of claim 1 further comprises receiving a second set of parameters to refine the set of related cases by increasing or decreasing the test for similarity between the patient specific information and the case histories in the database.

8. The method of claim 1 wherein the set of related case histories include diagnosis and treatment history for patients with diagnoses similar to the initial diagnosis information, and wherein using the set of related case histories to determine a set of parameters includes identifying indicators in the set of related case histories, an indicator indicating a medical condition of a patient, the indicators being part of the parameters.

9. The method of claim 8 wherein at least some indicators indicate corresponding molecular signatures and wherein the first diagnostic test corresponds to a test for the presence or absence of a molecular signature.

10. The method of claim 8 further comprising displaying the indicators on a screen showing a corresponding relevance of at least some of the indicators to the patient specific information.

11. The method of claim 1 wherein a related case history includes diagnosis, diagnostic test results, treatments information, and treatments results information.

12. The method of claim 1 further comprising receiving a selection of the diagnostic test and transmitting the selection to a computer for medical insurance approval.

13. A method of generating a customized summary of clinical data using a computer system, the customized summary being customized for a patient, the customized summary reflecting outcomes for patients with similar molecular signatures according to treatment options, the method comprising:

accessing a database to identify patient outcomes having similar molecular signatures to those of the patient, the database including patients histories information, the patients histories information including for at least some of the patients in the patients histories at least one corresponding molecular

signature identifying a diagnosed disease and a corresponding treatment history;

classifying the patient outcomes according to the treatments used in the identified patient outcomes; and

displaying the identified patient outcomes according to the corresponding treatments.

14. The method of claim 13 wherein accessing the database includes sending a description of the molecular signatures of the patient to the database and matching records in the database to the molecular signatures.

15. The method of claim 13 wherein displaying the identified patient outcomes includes generating a hyper-linked page where patient outcomes are shown as functions of the corresponding treatment and wherein hyper-links are associated with the treatments to provide additional information about the corresponding treatment.

16. The method of claim 15 wherein the hyper-linked page includes an HTML page.

17. The method of claim 13 wherein the displaying the identified patient outcomes includes generating an hyper-linked page where patient outcomes are shown as functions of the corresponding treatment and wherein hyper-links are associated with the treatments to provide additional information about the corresponding treatment.

18. The method of claim 13 wherein the displaying the identified patient outcomes includes generating an hyper-linked page where patient outcomes are shown as functions of the corresponding treatment and wherein hyper-links are associated with the treatments to provide additional information about the corresponding treatment.

19. The method of claim 13 wherein the displaying the identified patient outcomes includes generating an hyper-linked page where patient outcomes are shown as functions of the corresponding treatment and wherein hyper-links are associated with the treatments to provide additional information about the corresponding treatment.

20. The method of claim 13 further comprising receiving a selection of a treatment and transmitting that selection of the treatment to another computer for medical insurance approval.

21. A method of determining the relevancy of diagnostic tests from a database for a patient having an initial diagnosis, the method comprising:

searching the database to determine patient histories similar to the initial diagnosis;

identifying the occurrence of indicators in the patient histories, an indicator indicating a medical condition of a corresponding patient; and

displaying the relevancy of at least some of the diagnostic tests using the patient histories, at least some of the patient histories including a corresponding treatment and patient health history.

22. A system for providing diagnostic and treatment information to aid in the diagnosis and treatment of a patient, the system comprising:

a database including patient histories, at least some patient histories identifying a corresponding disease diagnosis, a treatment history, and a patient outcome;

a client including a program to receive diagnosis information and to display a set of indicators, the indicators indicating a medical condition in patient histories that are similar to the diagnosis information, the indicators further corresponding to diagnostic tests, the program further for receiving diagnostic test results and displaying patient outcomes according to treatment types; and

a server for querying the database and responding to requests from the client.

23. The system of claim 22 wherein the patient histories are stored in records, wherein the diagnosis information, diagnostic test results, and treatments for the patient are stored in the database.

24. The system of claim 22 further comprising a laser capture microdissection station to at least some of the diagnostic tests.

25. The system of claim 22 wherein the program displays hyper-links to link to descriptions of diagnostic test protocols to at least some of the diagnostic tests and to link descriptions of the indicators to the display of the indicators.

26. A system for generating a patient specific summary of clinical data, the customized summary being customized for a patient, the customized summary reflecting outcomes for patients with similar molecular signatures according to treatment options, the method comprising:

means for identifying patient outcomes having similar molecular signatures to those of the patient, the means for identifying including patients histories information, the patients histories information including for at least some of the patients in the patients histories at least one corresponding molecular signature identifying a diagnosed disease and a corresponding treatment history;

means for classifying the patient outcomes according to the treatments used in the identified patient outcomes; and

means for displaying the identified patient outcomes according to the corresponding treatments.

27. A system for determining the relevancy of diagnostic tests for a patient having a initial diagnosis, the method comprising:

means for searching for patient histories similar to the initial diagnosis;

means for identifying the occurrence of indicators in the patient histories, an indicator indicating a medical condition of a corresponding patient; and

means for displaying the relevancy of at least some of the diagnostic tests using the patient histories, at least some of the patient histories including a corresponding treatment and patient health history.

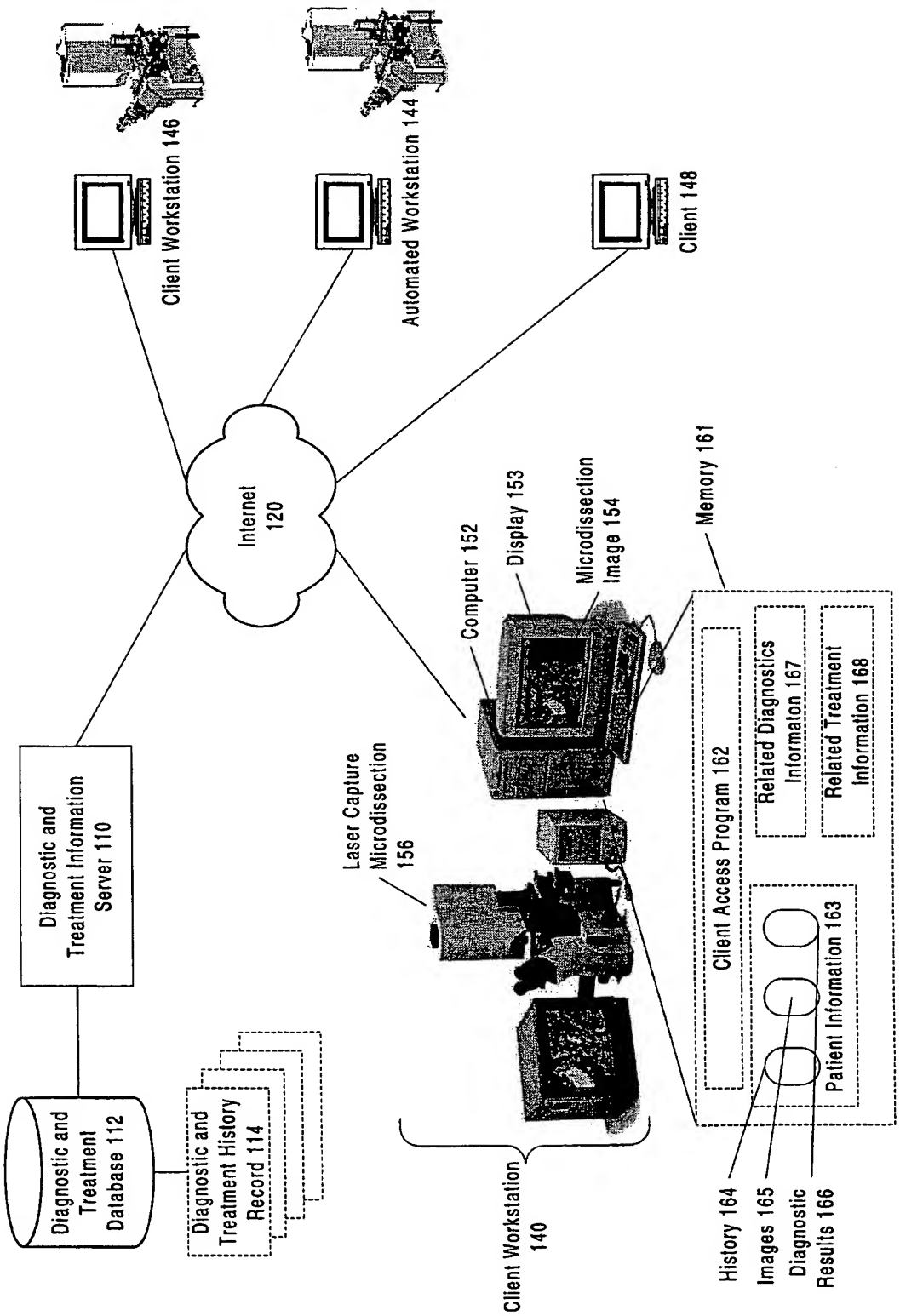
Client Workstation 146
Automated Workstation 144
Client 148
Internet 120
Diagnostic and Treatment Information Server 110
Diagnostic and Treatment Database 112
Diagnostic and Treatment History Record 114
Laser Capture Microdissection 156
Computer 152
Display 153
Microdissection Image 154
Memory 161
Client Access Program 162
Related Diagnostics Information 167
Related Treatment Information 168
Patient Information 163
Client Workstation 140
History 164
Images 165
Diagnostic Results 166

Figure 1

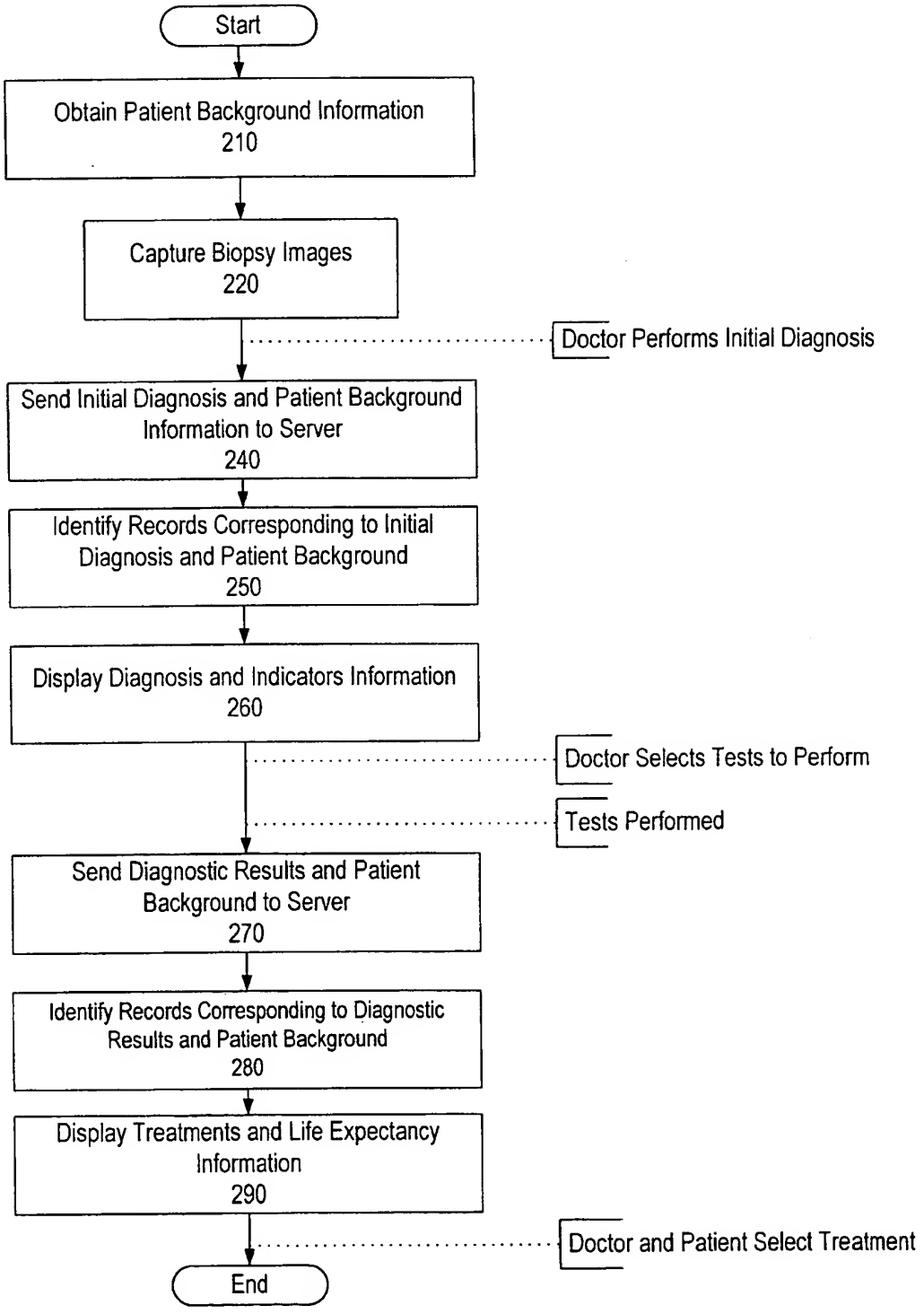
Start
Obtain Patient Background Information 210
Capture Biopsy Images 220
Doctor Performs Initial Diagnosis
Send Initial Diagnosis and Patient Background Information to Server 240
Identify Records Corresponding to Initial Diagnosis and Patient Background 250
Display Diagnosis and Indicators Information 260
Doctor Selects Tests to Perform
Tests Performed
Send Diagnostic Results and Patient Background to Server 270
Identify Records Corresponding to Diagnostic Results and Patient Background 280
Display Treatments and Life Expectancy Information 290
Doctor and Patient Select Treatment
End

Figure 2

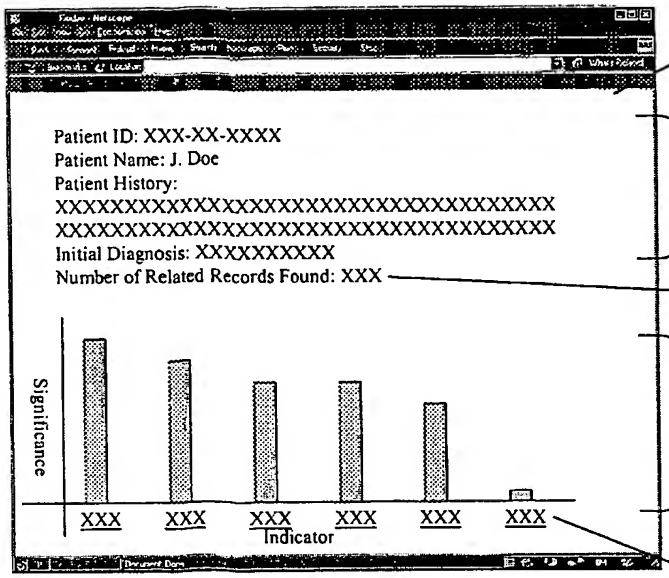


Figure 3

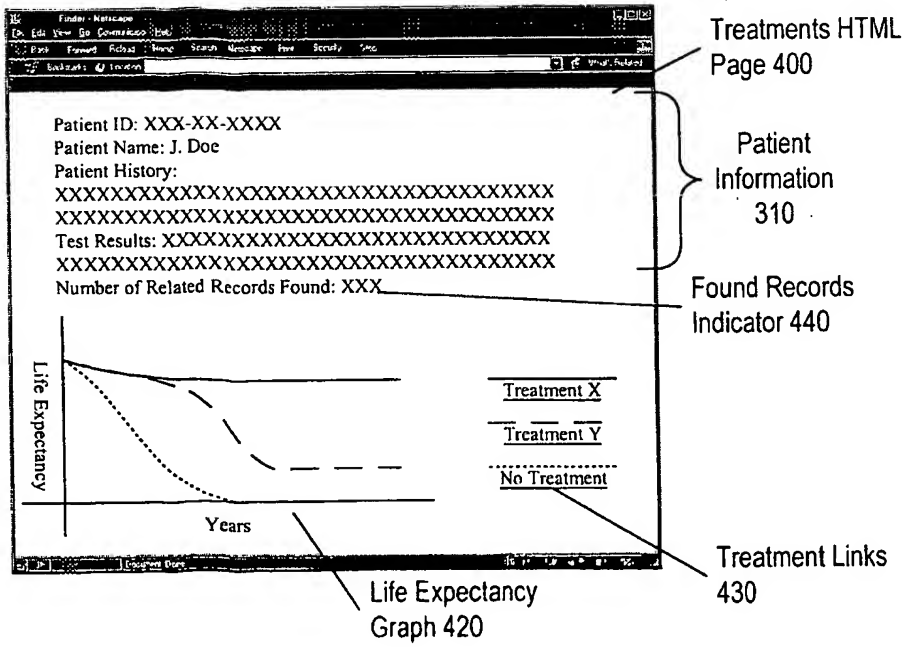


Figure 4

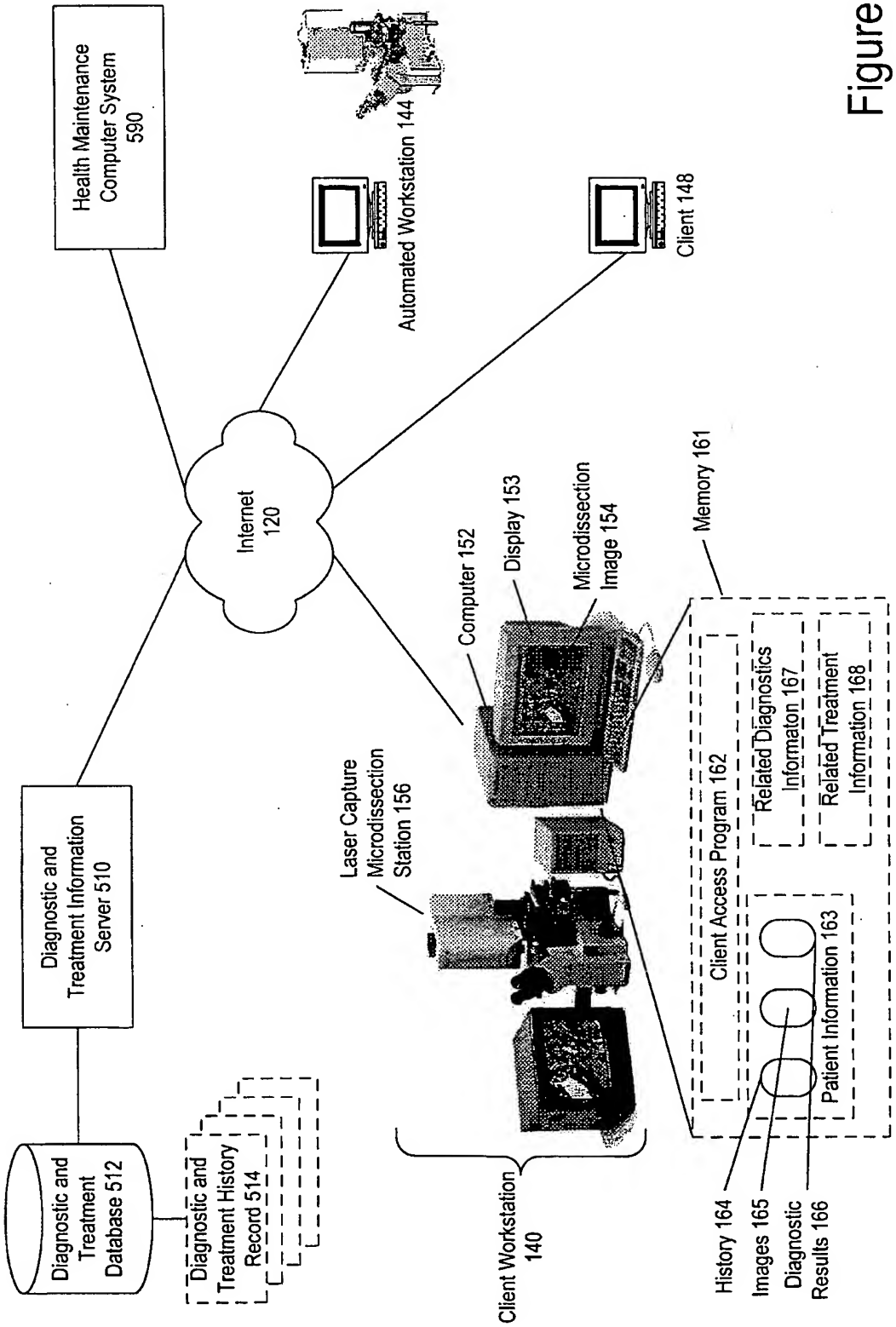
Health Maintenance Computer System 590
Automated Workstation 144
Client 148
Internet 120
Diagnostic and Treatment Information Server 510
Diagnostic and Treatment Database 512
Diagnostic and Treatment History Record 514
Laser Capture Microdissection Station 156
Computer 152
Display 153
Microdissection Image 154
Memory 161
Client Access Program 162
Related Diagnostics Information 167
Related Treatment Information 168
Patient Information 163
Client Workstation 140
History 164
Images 165
Diagnostic Results 166

Figure 5

# INTERNATIONAL SEARCH REPORT

Inte' 'onal Application No
PCT/US 99/15258

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G06F19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
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| Y | EP 0 332 322 A (ELSEVIER SCIENCE PUBLISHING CO) 13 September 1989 (1989-09-13)<br><br>column 4, line 3 -column 9, line 58 | 1-11,13, 14, 21-23, 26,27 |
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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"P" document published prior to the international filing date but later than the priority date claimed

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"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 25 October 1999 | 05/11/1999 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,<br>Fax: (+31–70) 340–3016 | Schenkels, P |

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# INTERNATIONAL SEARCH REPORT

Inte· ·ional Application No
PCT/US 99/15258

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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| A | MARSH A: "The application of 3D visualisation techniques for telemedical diagnosis"<br>IMAGING SCIENCES AND DISPLAY TECHNOLOGIES, BERLIN, GERMANY, 7-10 OCT. 1996,<br>vol. 2949, pages 203-213, XP002120132<br>Proceedings of the SPIE - The International Society for Optical Engineering, 1997, SPIE-Int. Soc. Opt. Eng, USA<br>ISSN: 0277-786X<br>page 203, line 1 -page 212, line 15 | 15-19,25 |

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